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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,187	01/13/2006	Rhonda Hansen	20366-124US1	3472

7590 05/22/2007

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
05/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,187	HANSEN, RHONDA	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-30 are pending in the instant application.

Claims 1-30 are subject to restriction as detailed below:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 5 and 19, drawn to a method for inhibiting a cancerous phenotype of a cell, comprising contacting a cancerous mammalian cell with an agent for inhibition of DKFZp566I133 activity, wherein the agent is a small molecule, classifiable in class 530, subclass 350, for example.

II. Claims 5 and 19, drawn to a method for inhibiting a cancerous phenotype of a cell, comprising contacting a cancerous mammalian cell with an agent for inhibition of DKFZp566I133 activity, wherein the agent is an antibody, classifiable in class 424, subclass 134.1, for example.

III. Claims 5, 7, and 19, drawn to a method for inhibiting a cancerous phenotype of a cell, comprising contacting a cancerous mammalian cell with an agent for inhibition of DKFZp566I133 activity, wherein the agent is an antisense polynucleotide or RNAs molecule, classifiable in class 514, subclass 44, for example.

IV. Claims 9-16, drawn to a method for detecting a cancerous cell, comprising detecting a level of DKFZp566I133 or fragment thereof in a test sample obtained from a cell of a subject, comparing the level of DKFZp566I133 to

a control level of DKFZp566I133 wherein the presence of a cancerous cell is indicated by detection of said level and comparison to a control level of DKFZp566I133, classifiable in class 435, subclass 6.

V. Claim 20, drawn to a method for assessing the tumor burden of a subject comprising detecting a level of DKFZp566I133 in a test sample from a subject, wherein the level of DKFZp566I133 in the test sample is indicative of the tumor burden in the subject, classifiable in class 435 subclass 91.1, for example.

VI. Claims 21-29, drawn to a method for identifying an agent that modulates a biological activity of a gene product differentially expressed in a cancerous cell as compared to a normal cell comprising, contacting a candidate agent with a DKFZp566I133; and detecting modulation of a biological activity of DKFZp566I133 relative to a level of biological activity of DKFZp566I133 in the absence of the candidate agent, classifiable in classes 536, subclass 24.5, class 424, subclass 134.1, or class 530, subclass 350, for example.

VII. Claim 30, drawn to an isolated polynucleotide comprising at least 15 contiguous nucleotides of a sequence selected from SEQ ID NOs: 1-499, classifiable in class 536, subclass 24.5, for example.

Claims 1-4, 6, 8, 17, and 18 links the inventions of Groups I-III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 1-4, 6, 8, 17, and 18 links. Upon the allowance of the linking claim(s), the

restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other, because of the following reasons:

Groups I-III are directed to related inventions. However, the related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions of Groups I-III patentably distinct from each other since they are directed to methods of using distinct and independent agents for inhibition of DKFZp566I133. The methods of using distinct and independent agents for inhibition of DKFZp566I133 of Groups I-III are known in the art to possess materially different designs. For example, the small molecule agent for inhibition of DKFZp566I133 of Group I comprises a

uniquely distinct and independent structure from the antibody agent for inhibition of DKFZp566I133 of Group II, or the antisense agent for inhibition of DKFZp566I133 of Group III. Therefore, a search of the small molecule agent for inhibition of DKFZp566I133 of Group I would not necessarily reveal art against the antibody agent for inhibition of DKFZp566I133 of Group II, or the antisense agent for inhibition of DKFZp566I133 of Group III. Similarly, a search of the antibody agent for inhibition of DKFZp566I133 of Group II would not necessarily reveal art against the antisense agent for inhibition of DKFZp566I133 of Group III. Because these groups utilize unique structures, namely, distinct antisense oligonucleotides, antibodies, and small molecule inhibitors, the inventions are therefore not obvious variants, which further substantiates that the inventions possess materially different designs. Furthermore, the inventions of Groups I-III are considered to be mutually exclusive, each from the other, since the components of one Group is not disclosed as requiring the components of another Group. Since it is a burden to search and examine these multiple inventions in a single application, due to the fact that the searches are divergent and non-coextensive, restriction is proper therefore.

Group IV is drawn to a method for detecting a cancerous cell, comprising detecting a level of DKFZp566I133 or fragment thereof in a test sample obtained from a cell of a subject, comparing the level of DKFZp566I133 to a control level of DKFZp566I133 wherein the presence of a cancerous cell is indicated by detection of said level and comparison to a control level of DKFZp566I133 and is considered to be distinct from the method for assessing the tumor burden of a subject comprising

detecting a level of DKFZp566I133 in a test sample from a subject, wherein the level of DKFZp566I133 in the test sample is indicative of the tumor burden in the subject of Group V. The inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method of Group IV is distinct from the method of Group V since both methods recite distinct method steps and distinct objectives. Furthermore, Group IV is distinct from Group V since the two Groups do not overlap in scope as each Group recites materially distinct methods which differ in criteria for success. Because these groups utilize unique and different method steps, the inventions are also therefore not obvious variants, and have a materially different design. Accordingly, restriction between these Groups is considered proper.

Group IV is drawn to a method for detecting a cancerous cell, comprising detecting a level of DKFZp566I133 or fragment thereof in a test sample obtained from a cell of a subject, comparing the level of DKFZp566I133 to a control level of DKFZp566I133 wherein the presence of a cancerous cell is indicated by detection of said level and comparison to a control level of DKFZp566I133 and is considered to be distinct from the method for identifying an agent that modulates a biological activity of a gene product differentially expressed in a cancerous cell as compared to a normal cell, comprising, contacting a candidate agent with a DKFZp566I133; and detecting modulation of a biological activity of DKFZp566I133 relative to a level of biological

activity of DKFZp566I133 in the absence of the candidate agent of Group VI. The inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method of Group IV is distinct from the method of Group VI since both methods recite distinct method steps and distinct objectives. Furthermore, Group IV is distinct from Group VI since the two Groups do not overlap in scope as each Group recites materially distinct methods which differ in criteria for success. Because these groups utilize unique and different method steps, the inventions are also therefore not obvious variants, and have a materially different design. Accordingly, restriction between these Groups is considered proper.

Group V is drawn to a method for assessing the tumor burden of a subject comprising detecting a level of DKFZp566I133 in a test sample from a subject, wherein the level of DKFZp566I133 in the test sample is indicative of the tumor burden in the subject and is considered to be distinct from the a method for identifying an agent that modulates a biological activity of a gene product differentially expressed in a cancerous cell as compared to a normal cell, comprising, contacting a candidate agent with a DKFZp566I133; and detecting modulation of a biological activity of DKFZp566I133 relative to a level of biological activity of DKFZp566I133 in the absence of the candidate agent of Group VI. The inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious

variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method of Group V is distinct from the method of Group VI since both methods recite distinct method steps and distinct objectives. Furthermore, Group V is distinct from Group VI since the two Groups do not overlap in scope as each Group recites materially distinct methods which differ in criteria for success. Because these groups utilize unique and different method steps, the inventions are also therefore not obvious variants, and have a materially different design. Accordingly, restriction between these Groups is considered proper.

Group VII is related to Group III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated polynucleotide comprising at least 15 contiguous nucleotides of a sequence selected from SEQ ID NOs: 1-499 of Group III can be used in a materially different process such as a process for identifying an agent that modulates a biological activity of a gene product differentially expressed in a cancerous cell as compared to a normal cell, which is a materially different process than the method for inhibiting a cancerous phenotype of a cell, comprising contacting a cancerous mammalian cell with an antisense agent for inhibition of DKFZp566I133 activity of Group III. Because these inventions are independent or distinct for the reasons given above and there would be a serious

burden on the Examiner if restriction were not required because the inventions require a different field of search (see MPEP 808.02), restriction for examination purposes as indicated is proper.

If Group VII is elected, claim 30 is subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claim 30 specifically claims an isolated polynucleotide comprising at least 15 contiguous nucleotides of a sequence selected from SEQ ID NOs: 1-499. Although the sequences claimed are allegedly gene products differentially expressed in cancerous breast cells, the instant sequences are considered to be unrelated, since each

sequence claimed is structurally and functionally independent and distinct for the following reasons: each sequence has a unique nucleotide sequence and each sequence is targeted to a different and specific gene (per Applicant's Tables 1 and 11 in the specification). As such the Markush/genus of sequences in claim 30 is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the sequences claimed in claim 30 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) sequence from claim 30. Note that this is not a species election but a restriction of distinct and independent inventions: unique and structurally distinct nucleotide sequences.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To

reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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May 17, 2007